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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/788,264	02/16/2001	William H. Fleming	6122-54472	8684

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EXAMINER	
STEPHENS, JACQUELINE F	

ART UNIT	PAPER NUMBER
3761	8

DATE MAILED: 12/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/788,264	FLEMING, WILLIAM H.	
	Examiner	Art Unit	
	Jacqueline F Stephens	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-26,28-40 and 46* is/are rejected.

7)☒ Claim(s) *5,27 and 41-45* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☒ Interview Summary (PTO-413) Paper No(s). 7.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1, and 3-46 have been considered but are moot in view of the new ground(s) of rejection.

Specification

2. Applicant is reminded of the proper format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Objections

3. Claims 28 and 46 are objected to because of the following informalities: Claim 28 recites the limitation "the posterior portion" in line 4 and "the anterior portion" in line 8. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1, 3, 4, 7-11, 15, and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenbluth et al. USPN 5074855.

As to claim 1, Rosenbluth discloses an interlabial delivery device **10** comprising a pad **12**, wherein the pad is configured to be retained between labia of a subject and the pad carries a therapeutically or diagnostically effective amount of a diagnostic or therapeutic agent (col. 2, lines 27-37 and col. 5, lines 7-11). The pad has a minor portion superimposed on a major portion, the minor portion having a cross-sectional area smaller than a cross-sectional area of the major portion and wherein the minor portion is tapered to facilitate insertion between the labia and retention in the interlabial space (Figures 1-6).

As to claim 3, Rosenbluth discloses the pad is a highly absorbent non-swellable material (col. 3, lines 26-33).

As to claim 4, see col. 2, lines 27-37 and col. 4, lines 54-63.

As to claims 7, 9, and 11, see col. 5, lines 7-11.

As to claim 10, the device of Rosenbluth comprises a leading anterior portion and a posterior portion (col. 4, lines 26-43), which are capable of fitting in an intravaginal and extravaginal region, respectively. Furthermore, Rosenbluth discloses the treatment is applied to the surface of the interlabial device (col. 5, lines 7-11), therefore, the intravaginal portion carries the agent to be delivered.

As to claim 15, Rosenbluth discloses a method of treating a disease, wherein the device is a pad that carries a therapeutically effective amount of an active agent, or the agent has already been applied to the labia or administered intra-vaginally prior to the placing the pad in the interlabial space (col. 5, lines 7-11); and retaining the pad in the interlabial space (col. 2, lines 27-37) where it is capable of dispensing or retaining the therapeutic agent.

As to claim 17, see col. 4, lines 26-43.

As to claim 18, Rosenbluth discloses the pad has a leading anterior portion and that the user inserts the pad into the interlabial space by way of the leading anterior portion (col. 4, lines 26-43). It is well known in the art that the interlabial space does not

include the vaginal orifice, but the area external of the vaginal orifice. Furthermore, Hirschman discloses the pad is retained in the interlabial space (col. 2, lines 27-37), which includes opposing labia. Regarding the limitation of "a width, which is wider than a normal anatomic interlabial space", applicant has not defined a normal anatomic interlabial space, which obviously can vary depending on the user. The fact that the pad of Hirschman is firmly retained in the interlabial space indicates it has sufficient width (in the posterior portion), which is wider than a 'normal' anatomic interlabial space.

As to claim 19, see Figures 1-7.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 3, 4, 6-26, 28-40, and 46 as best understood by the examiner, are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirschman USPN 3983873 in view of Osborn, III et al. USPN 6409713.

As to claim 1, Hirschman discloses an interlabial device comprising a pad, wherein the pad is configured to be retained between labia of a subject and the pad (Abstract). The pad has a minor portion superimposed on a major portion, the minor

portion having a cross-sectional area smaller than a cross-sectional area of the major portion (Figures 1-14). The minor portion is tapered to facilitate insertion between the labia and retention in the interlabial space (Abstract). Hirschman does not disclose the interlabial device carries a therapeutically or diagnostically effective amount of a diagnostic or therapeutic agent. Osborn discloses an interlabial delivery device, which carries a therapeutically or diagnostically effective amount of a diagnostic or therapeutic agent for the benefit of preventing drying of the wearer's labial tissue and to reduce friction of the structure against the wearer's labial tissue (Osborn, Abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the interlabial device of Hisrchman to have a therapeutically or diagnostically effective amount of a diagnostic or therapeutic agent for the benefits disclosed in Osborn.

As to claim 3, Hisrchman/Osborn discloses the pad is a highly absorbent non-swellable material (Hirschman col. 2, lines 61-64).

As to claim 4, see Hirschman figures 1-14 and Hirschman Abstract.

As to claim 6, see Hirschman figures 13-15.

As to claims 7-9, and 11-14 see Osborn col. 25, lines 45-59.

As to claim 10, the device of Hirschman/Osborn comprises a leading anterior portion and a posterior portion (Hirschman col. 3, lines 3-10), which are capable of fitting in an intravaginal and extravaginal region, respectively. Furthermore, Hirschman/Osborn disclose the treatment is applied to the body-contacting surface of the interlabial device (Osborn col. 26, lines 36-45), therefore, intravaginal portion carries the agent to be delivered.

As to claim 15, 20, and 21, Hirschman/Osborn disclose a method of treating a disease (Osborn col. 25, lines 45-59 disclose the delivery device comprises treatment additives), wherein the device is a pad that carries a therapeutically effective amount of an active agent, or the agent has already been applied to the labia or administered intra-vaginally prior to the placing the pad in the interlabial space (Osborn, Abstract; col. 25, lines 45-59; col. 26, lines 36-45); and retaining the pad in the interlabial space (Hirschman col. 3, lines 5-10) where it is capable of dispensing or retaining the therapeutic agent. Because the pad surface contains the treatment, the method encompasses the peri-labial area and a method of delivering translabially.

As to claim 16, see Hirschman Abstract and col. 3, lines 5-10.

As to claim 17, see Hirschman col. 3, lines 3-30.

As to claim 18, Hirschman/Osborn discloses the pad has a leading anterior portion and that the user inserts the pad into the interlabial space by way of the leading anterior portion (Hirschman col. 3, lines 5-7). It is well known in the art that the

interlabial space does not include the vaginal orifice, but the area external of the vaginal orifice. Furthermore, Hirschman discloses the pad is retained in the interlabial space (col. 3, lines 5-10), which includes opposing labia. Regarding the limitation of "a width, which is wider than a normal anatomic interlabial space", applicant has not defined a normal anatomic interlabial space, which obviously can vary depending on the user. The fact that the pad of Hirschman is firmly retained in the interlabial space indicates it has sufficient width (in the posterior portion), which is wider than a 'normal' anatomic interlabial space.

As to claim 19, see Figures 1-12 of Hirschman.

As to claim 22, Hirschman/Osborn disclose a method for administering a drug to a subject, comprising inserting a pad impregnated with the drug (Osborn, Abstract; col. 25, lines 45-59; col. 26, lines 36-45) into the subject's interlabial space and positioning the pad against the subject's external vaginal orifice - Hirschman/Osborn discloses the user inserts the pad into the interlabial space by way of the leading anterior portion (Hirschman col. 3, lines 5-7). It is well known in the art that the interlabial space does not include the vaginal orifice, but the area external of the vaginal orifice. The pad is devoid of corners and flat surfaces (Hirschman Figures 13 and 14). The pad has a minor portion superimposed on a major portion (Hirschman Figures 13 and 14). The minor portion has a cross-section area smaller than a cross-section area of the major portion (Hirschman Figures 13 and 14). Both the minor and major portion are

curvilinear in cross-section (Hirschman Figures 13 and 14). The minor portion facilitates insertion between the subject's labia and retention in the interlabial space (Hirschman col. 3, lines 5-10) and retaining the pad in the interlabial space to dispense the drug interlabially(Osborn col. 25, lines 45-59 , col. 26, lines 36-45) disclose the delivery device comprises treatment additives), wherein the device is a pad that carries a therapeutically effective amount of an active agent) where it is capable of dispensing or retaining the therapeutic agent.

As to claim 23, see Hirschman Figures 1-14.

As to claim 24, Hirschman/Osborn discloses the pad has a leading anterior portion and an elongated posterior portion (Hirschman Figures 1-14). The user inserts the pad into the interlabial space by way of the leading anterior portion (Hirschman col. 3, lines 5-7). It is well known in the art that the interlabial space does not include the vaginal orifice, but the area external of the vaginal orifice.

As to claims 25, 26, 39, 40, and 46 see Osborn col. 25, lines 45-59 and col. 26, lines 36-45.

As to claim 28, Hirschman/Osborn discloses a method of treating a symptom of a subject (Osborn col. 25, lines 45-59 disclose the delivery device comprises treatment additives), comprising positioning an interlabial elongated absorbent pad such that the pad is retained between the labia external to the subject's vaginal orifice (Osborn,

Abstract; col. 25, lines 45-59; col. 26, lines 36-45). Hirschman/Osborn discloses the user inserts the pad into the interlabial space by way of the leading anterior portion (Hirschman col. 3, lines 5-7). It is well known in the art that the interlabial space does not include the vaginal orifice, but the area external of the vaginal orifice. The pad has a longitudinally extending minor portion integrated with a longitudinally extending major portion (Hirschman Figures 1-14). The minor portion has a smaller transverse section diameter relative to the larger transverse section diameter of the major portion (Hirschman Figures 1-14). The minor portion facilitates insertion between the subject's labia and retention in the interlabial space, which is adjacent to the vaginal opening (Hirschman col. 3, lines 5-10) and retaining the pad in the interlabial space (Hirschman col. 3, lines 5-10 and Abstract), where it is capable of reducing the symptom (Osborn Abstract and col. 25, lines 45-59) and retaining the pad in the interlabial space (Hirschman, Abstract).

As to claims 29, 31-38, see Hirschman Figures 1-14.

As to claim 30, Hirschman discloses the pad is self-retained (col. 3, lines 7-10), which indicates no adhesive is used to retain the pad.

Allowable Subject Matter

8. Claims 5, 27, and 41-45 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline F Stephens whose telephone number is (703) 308-8320. The examiner can normally be reached on Monday-Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703)308-1957. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Jacqueline F Stephens
Examiner
Art Unit 3761

December 17, 2003

WEILUN LO
SUPERVISORY PATENT EXAMINER
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